

REMARKS

Claims 1-3, 7, 8, 12, 16 and 17 are pending. Favorable reconsideration is respectfully requested.

The rejections of the claims under 35 U.S.C. 103(a) over WO 97/20555 (hereinafter referred to as "WO '555") alone or in combination with Wurtman (U.S. 4,687,763) are respectfully traversed. Those references fail to suggest the claimed invention.

The present invention relates to a method for the treatment of brain edema, comprising administering an effective amount of a composition comprising melatonin to a subject having brain edema. See Claim 1. Thus, the subject treated according to the claimed invention is actually afflicted with brain edema.

Both Applicants and the Examiner agree that brain ischemia can cause brain edema. As the Examiner notes in the Answer, the present specification states that the edema can cause additional ischemia. See the present specification at the paragraph bridging pages 2 and 3.

Applicants and the Examiner also agree that WO '555 describes administering melatonin to treat brain ischemia. In removing the rejection under 35 U.S.C. §102(b), the Examiner agrees that WO '555 does not explicitly or inherently disclose the treatment of brain edema.

Rather, the Examiner argues:

Since ischemia is the causative factor of brain edema, it would have been obvious to one of ordinary skill in the art that a composition, which is able to prevent ischemia, would be preventing the edema also. [Examiner's Answer at page 3, last paragraph.]

However, as discussed above, the claimed invention relates to a method of treating a subject actually suffering from brain edema, and not to a method of preventing brain edema.

For that reason alone, the Office has failed to make out a prima facie case of obviousness over WO '555.

In addressing Dr. Torii's Declaration, the Examiner states:

First of all, the examiner would like to note that the declaration is not based on any experimental evidence.
[Examiner's Answer at page 4, lines 4-5.]

Appellants are not aware of any rule or case law which requires that a Declaration is somehow limited to the presentation of experimental evidence. See 37 C.F.R. §1.132.

The Examiner acknowledges Dr. Torii's opinion in stating:

while it is true that ischemia is the cause of brain ischemia, the fact that a subject has an ischemic brain injury does not mean that the subject must also have brain edema. [Examiner's Answer, page 4, lines 9-11.]

Significant by its absence is any argument or evidence in the record that Dr. Torii's statement to that effect is incorrect.

At the bottom of page 4 of the Answer, the Examiner states:

WO [i.e., WO '555] teaches 'ischemic [sic] injury and, one cannot rule out edema as a cause of the ischemia in WO. Therefore, WO, which is suggestive of treatment of ischemic injury treatment by melatonin, is also suggestive of treatment of edema.

However, the Examiner has provided no evidence at all to support the argument that the ischemia in the subjects treated in WO '555 was caused by edema. That is nothing but sheer speculation by the Examiner. And, even if the Examiner is correct, it is irrelevant. There is no indication in WO '555 that the melatonin would have treated the edema.

At page 5, line 10, the Examiner states "WO suggest [sic] the combination of melatonin and mannitol to reverse cerebral swelling" (emphasis removed). At page 13, lines 11-15, WO '555 explicitly states that the mannitol is "used to reverse cerebral swelling immediately upon initiating perfusion." There is no indication in WO '555 that melatonin can be used as the active agent to treat brain edema as claimed.

Wurtman discloses a composition containing melatonin for administration to an animal in order to increase the levels or release of brain serotonin. See the Abstract. There is no teaching in Wurtman that melatonin can be used as the active agent to treat brain edema as claimed. Therefore, the combination of WO '555 and Wurtman fails to suggest the claimed method.

In view of the foregoing, the claims are not obvious over WO '555 alone or in combination with Wurtman. Accordingly, withdrawal of these grounds of rejection is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

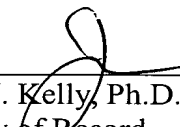
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